17 Third-Party Audit Programs for the Fresh-Produce Industry

Kenneth S. Petersen

Introduction

Over the past twenty years, the U.S. Centers for Disease Control and Prevention (CDC) have reported increased incidence of foodborne illnesses linked to fresh produce (U.S. CDC 2008); buyers of fresh produce are increasingly utilizing both second- and third-party audits to verify that their suppliers are taking effective precautionary steps to reduce the risk of microbial contamination of the produce. This chapter looks at the third-party audit, how it works, and what produce growers should expect when they are asked to supply a third-party audit to the purchasers of their products.

History

Since the 1960s when the Pillsbury Corporation developed the Hazard Analysis and Critical Control Point (HACCP) system for NASA to ensure food safety for manned space flights, third-party audits have been used by companies and the government to ensure that suppliers are following specific food safety practices. In the decades that followed, third-party audits became common in the processed foods and seafood industries, but the fresh produce industry generally did not adopt this practice.

With the increased incidence of foodborne illnesses associated with fruits and vegetables, President Clinton announced a plan entitled *Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables*. As part of this initiative, the U.S. Food and Drug Administration (FDA) partnered with the U.S. Department of Agriculture (USDA) to issue guidance on good agricultural practices (GAPs) and good manufacturing practices (GMPs) for fresh fruits and vegetables. In October 1998, the FDA issued the *Guidance for Industry—Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* (U.S. Food and Drug Administration 1998). It is important to note that the recommendations in the *Guide* are voluntary, and they are not enforceable under FDA regulations.

Since the release of the *Guide*, the FDA in partnership with the produce industry developed the *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables* (U.S. Food and Drug Administration 2008). Additionally, the produce industry, in collaboration with the FDA, developed commodity-specific guidance documents for tomatoes and melons (U.S. Food and Drug Administration 2005, 2006). These guidelines, also voluntary, provide recommendations that reflect the current state of thinking of leading food safety experts and serve as the basis for most industry-initiated requirements for growers.

In 1999, Safeway Inc. initiated a program requiring third-party food safety audits of its suppliers of "high-risk" produce. *High-risk* was initially limited to leaf lettuce, but then its meaning was expanded to include other items, and eventually included all fruits and vegetables that were Safeway Inc. purchases. Shortly thereafter, Albertson's Inc. requested its suppliers of fresh produce to verify safe production and packing practices. Specifically required were the development of safe production manuals and routine self- and third-party audits based on the sanitation standards provided in the FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*. Within several years, other major retail and food-service chains instituted third-party audits as a means of ensuring adherence to good agricultural and manu-facturing practices (Laborde 2000). In May 2006, the USDA Agricultural Marketing Service announced that all fruit and vegetable purchases made for feeding assistance programs such as the School Lunch Program would require third-party audits verify-ing that good agricultural and good handling practices were being followed (U.S. Department of Agriculture 2006).

Current Issues

There is no single "national standard" that the produce industry is following, and individual entities requiring third-party verification of GAPs determine their own audit standards and auditors. It is not uncommon for the same operation to be audited twice, thrice, or even more to satisfy the different requirements for various producers/proces-sors and buyers, leading growers to feel in a state of "audit fatigue" from the large number of different audits they go through during the year. Until a national standard that is accepted by the entire produce industry can be developed, or the entities requir-ing third-party audits accept audits from a wider range of auditing firms, this problem of "audit fatigue" appears likely to continue.

Definitions

The following terms are important to understand when discussing audits:

Audit: A planned, systematic, independent, and documented examination and review to determine whether activities and related results comply with planned arrange-ments and whether these arrangements are implemented effectively and suitably to achieve objectives (Surak and Wilson 2007).

Auditee: The individual or company who is being audited. This may or may not be the same entity that is the client.

Auditing Body: A company or government agency that performs audits. These audits may be first-, second-, or third-party.

Auditor: A member of the audit team performing the audit.

Client: The individual or company that requests an audit. The client sets the para-meters, or scope, of the audit and gives the authority to the auditor to perform the audit.

External Audit (Second- or Third-Party Audit): An audit performed by an entity not employed by the auditee. A second-party audit is an audit that is conducted by the buyer of the auditee's product.

Internal Audit (First-Party Audit): An audit performed by the auditee on its own system or process.

Lead Auditor: The individual designated by the auditing body to lead the audit team. This individual is responsible for all aspects of the planning, preparation, and conducting of the audit.

Third-Party Audit: A third-party audit is defined in the American Society for Quality Audit Handbook (Russell 2000) as an audit "that is performed by an audit organization independent of the customer-supplier relationship and is free of any conflict of interest." The independence of the audit organization is critical in ensuring that the third-party audit is neutral and impartial in its assessment of the safety of the food handling system.

Third-Party Audit Standard: Third-party audits are performed by auditing organizations to evaluate the auditee's system or process and establish compliance with mutually agreed upon criteria. The criteria are usually either "client-developed standards" or an "industry standard" that is frequently utilized in that industry. The leafy greens industry relies on the *Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens* (California Department of Food and Agriculture 2007) as the standard for audits carried out by the USDA and the California Department of Food and Agriculture in California and Arizona. Auditing organizations such as *GlobalGAP* and *Safe Quality Food* (SQF) have defined standards that are also widely used in the industry.

Preparing for a Third-Party Audit

It is important for operations to be prepared for third-party audits at any time by knowing the applicable audit standards and working vigilantly to maintain compliance. Because there are many different audit standards used in the produce industry, it would not be feasible to cover all the aspects of the different audit standards here. Instead, the next several sections will cover in a more general way the major components of preparing for third-party audits. The most critical element in being prepared for third-party audits is having a working food safety program. To be successful, this program requires careful planning and thorough implementation so that it is ingrained into the practices of every employee and every component of the operation.

Development and Implementation of a Food Safety Plan

Food safety plans outline the policies and procedures auditees follow to conform to audit standards and serve as the foundation of the working food safety program. Food safety plans are developed in one of two ways: hiring an outside consultant or having the auditee critically evaluate its own operation. Both approaches are widely used in the produce industry, but it is recommended that an auditee develop and implement its own food safety plan.

The first step in developing a food safety plan is identifying specific risks within the operation, similar to the first step operations followed under a HACCP program. Once a hazard analysis has been conducted, policies and procedures can be used to develop Standard Operating Procedures (SOPs) to minimize the risks of microbial contamination occurring. The following excerpt helps define SOPs (U.S. Environmental Protection Agency 2007):

SOPs detail the regularly recurring work processes that are to be conducted or followed within an organization. They document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality.

SOPs are initially developed using current local, state, or federal regulations and requirements outlined in the audit standard, and the SOPs often codify policies and procedures already practiced, but not formally documented previously. The SOP should be written so that the target audience finds it understandable and usable without requiring constant supervision. Copies of the SOPs should be available (both in hard copy and electronic format) and readily accessible for reference in the work areas of individuals performing the activity. SOPs can also be made available in foreign languages, if appropriate, to help prevent deviations from the SOP. Even the most well-written SOPs can fail, if they are not followed properly, and management needs to review and encourage the use of SOPs. The SOPs should outline how and what will be documented in a record (documentation is covered later in this chapter). For many operations, the initial implementation of a food safety plan and its associated SOPs may constitute a cultural change, but adapting to these changes is necessary to successfully meet audit requirements.

Food safety plans do not need to be complex, and often simpler plans, if written correctly, work better. It is important to evaluate each policy directive and to make sure that each is obtainable and useful. As auditors observe an operation, they note any policy or procedure in the plan that is not being followed as "out of compliance" in the final audit report. If the maximum number of "out of compliance" issues allowed in an audit standard is exceeded, the auditee fails to meet the requirements of the audit standard. Care must be taken to avoid putting anything in the plan that is unobtainable or frivolous that could jeopardize meeting the requirements of the audit standard. An example of an unobtainable or frivolous policy in a food safety plan would be having an SOP requiring restroom facilities to be cleaned every hour. Suppose for the sake of this example that the usage of that restroom facility is such that cleaning it once daily suffices in maintaining a clean and hygienic facility. If the facilities are cleaned once daily and recorded in written documentation, this situation would not be in compliance with the auditee's policy, even if the facilities are clean throughout the day. Compliance, in this case, requires that the restroom facilities must be cleaned every hour, even if they have not been used. Such a policy would be considered unobtainable or frivolous. The policy should be revised to something like "restroom facilities will be checked every hour for cleanliness, and cleaned if found to be dirty and, at a minimum, cleaned once per day." In this case, the restroom facilities need only to be checked every hour, and cleaned only if dirty, at a minimum of once daily. The written documentation of the daily cleanings, as mentioned above, would suffice to ensure compliance with the auditee's policy.

Training

It is important to understand the training requirements of the audit standard and the auditee's food safety plan in order to successfully implement a food safety program. Once a food safety plan has been developed, management should arrange to train all those who are covered by the plan so that they understand and abide by it. Training

should be viewed as a continuous process, whether to educate new hires; to give employees a refresher on the plan; or to get feedback on what works, what does not, and what can be improved. An audit standard may require that someone in the operation will receive specific training in food safety or HACCP and that someone must attend meetings throughout the year in order to maintain certification to that standard.

Documentation

If it's not documented, it didn't happen.

Properly documenting observations during an audit is as important as the actual observations themselves, because it provides the only source of information an auditor can review with regard to an auditee's adherence to a food safety plan. These records are vital in demonstrating an auditee's compliance with established food safety regulations, if an auditee is ever investigated by a local, state, or federal health department or agency. Most audit standards outline the documentation that is required and the documentation that the auditee identified as necessary during the development of its food safety program. Many local cooperative extension services and commercial audit companies have developed templates that can assist the auditee in preparing to properly document activities. In all cases, documentation should be legible, clear, concise, and to the point to provide the auditee and the auditor a clear picture of what happened. A good rule of thumb for documentation is to cover the "Five Ws and H" of investigative journalism; the *who*, *what*, *where*, *when*, *why*, and *how*. All documentation and records should cover these questions to facilitate the auditor's evaluation of the process. Figure 17.1 provides a sample training record that answers the Five Ws and H: Who was trained, What they were trained to do, Where and When they were trained, Why they were trained, and How they were trained.

Internal Audits and Third-Party Audits

Internal audits and third-party audits both serve as a way to make continual improvements to the food safety plan. Continual improvements assist the auditee in making sure that the food safety program does not become out of date or obsolete.

Internal Audit and Verification

Once the food safety plan has been implemented, the auditee should perform internal audits of the operation to verify that the food safety plan is being followed properly and working out as it was intended. Internal audits are an excellent way for management to "shake down" the plan and make sure that it is working effectively. If something is found not to be working, it gives management an opportunity to address the issue and fix it before an outside auditor comes in. It may take several internal audits to work out the kinks in a newly implemented food safety program, but once the program has been established, internal audits may need to be performed only routinely on a yearly basis or whenever there is a major change in the operation that affects the identified risks in the food safety program. In some audit standards, internal audits are a required component of a food safety program. Internal audits should be documented, including the results and any corrective actions taken, if necessary.

Employee Training Form for Worker Health and Hygiene
Ed Range Produce Co, Blairstown, NJ

In accordance with ABC Produce Company Food Safety Plan, the following employees were trained on proper hand washing and personal hygiene using the Cornell University Training video *Fruits, Vegetables, and Food Safety: Health and Hygiene on the Farm.*

Trainer: _____   Location:_____

Date:_____

By signing below, I acknowledge that I have received and understand the training received on proper hand washing and personal hygiene. If I have questions about this training in the future, I will contact my immediate supervisor.

Employee Name (please print)   Employee Signature:

1. Miguel Sonora   M Sonora
2. Ging Lee   Ging Lee
3. Ivan Peppelski   Ivan Peppelski
4. Budwada Unifemi   Budwawa Unifemi
5. John Doe   John Doe

Employee Training Form 01 (10/07)

Figure 17.1. An example of a training record.

Scheduling a Third-Party Audit

Once the auditee feels comfortable that its food safety program is in place and functioning well in terms of meeting the criteria for a third-party audit as outlined in the audit standard, the auditee should contact the appropriate auditing body. Most auditing bodies have an audit program coordinator that handles all audit requests and scheduling of audits and personnel. When speaking to the coordinator for the first time, be prepared to describe the operation, identify the applicable audit standard, and answer any other questions that he/she may have. The coordinator will collect the basic information about the auditee and forward it to the lead auditor, who serves as the contact between the auditing body, auditee, and client. The lead auditor contacts the auditee and client (often the same entity in the produce industry) to gather more specific information about the scope of the audit and schedule a date to perform the audit. The lead auditor develops an audit plan that includes such things as an estimate of the time needed to conduct the audit; the number of auditors required; and any other details needed to plan, prepare, and conduct the audit. Prior to the audit, the lead auditor may ask for a copy of the food safety plan and maps of the farm or operation for review, an escort or guide for the day of the audit, and access to a room for the audit team to

compile the audit report at the conclusion of the audit. If the auditee's employees predominately speak a foreign language, the lead auditor may also ask for a translator to be provided.

Audit Day

All audits start with an opening meeting and finish with a closing meeting. The auditee (and/or client) management should be present at both meetings. At the opening meeting, the lead auditor introduces the audit team, outlines the audit plan, discusses timelines, requests documentation and records, and indicates that the audit team will be interviewing employees, as necessary. Auditors interview employees to verify that policies and procedures outlined in the food safety plan are being followed. It is generally beneficial for the auditee to notify employees that an audit is scheduled and that they may be interviewed by an auditor prior to the audit.

After the opening meeting, auditors have the discretion to go anywhere in the operation at any time, but usually they request that the escort or guide bring them to the beginning of the process to follow the product through to the end of the process. For produce operations, the auditors usually start in the fields during harvest, and they finish in a packinghouse or storage facility, depending on the scope of the audit. The escort or guide should provide access to the facility, not lead the audit team through "a dog and pony show" that may raise suspicions and cause the team to want to dig deeper and find out what the auditee might be hiding.

Once the fact-finding portion of the audit is completed, the audit team will meet internally to discuss individual observations, review interview notes, and prepare the final audit findings. Once that process is completed, a closing meeting is held. At the closing meeting, the lead auditor will discuss the findings of the audit and give the auditee management the opportunity to discuss, clarify, or dispute any findings, as appropriate. A copy of the audit report is given to the auditee, and, depending on the applicable audit standard, corrective action reports that require follow-up actions are issued.

Corrective Action Reports

The auditor issues corrective action reports for any observations or records that indicate noncompliance. Figure 17.2 shows a representative simple corrective action report using the restroom cleaning example used earlier in this chapter. Depending on the severity of the nonconformity, the corrective action report may require that the auditee address the issue in a certain period of time or require that the auditor perform a follow-up audit to verify that the auditee took appropriate corrective action to fix the problem. Corrective actions can be identified as either short-term or root-cause corrective actions. Short-term corrective actions are immediate steps to correct a specific issue. Root-cause corrective actions are long-term actions that look to solve habitual problems within a system. For example, an employee is found not to be wearing a hairnet, and there is a policy for all employees to wear hairnets. A short-term corrective action would be removing that employee from the area to put on a hairnet. If there are multiple employees not wearing hairnets and the issue recurs and is documented over a significant period, a root-cause analysis would be done. This analysis might show that the employees were not trained properly with hairnets, did

<div style="text-align: center;">

NOTICE OF CORRECTIVE ACTION
ABC AUDITNG COMPANY, Washington DC

</div>

Name of Auditee: Ed Range Produce Co.   **Date:** January 15, 2008
Auditor Name: Ken Petersen

OBSERVATION:
During a records review of Ed Range Produce Co.'s restroom cleaning schedule, records indicate that the restrooms were only cleaned 1 time a day for the period December 15, 2007, to present. Records indicated that the maintenance supervisor performed this function and initialed the "Restroom Cleaning Log" when the task was completed. When the maintenance supervisor was interviewed, he indicated that he did only clean the bathrooms once daily during the time frame above. When auditor showed maintenance supervisor the restroom cleaning policy (page 7 of the Ed Range Produce Co SOP Manual) which states the restrooms are to be cleaned every hour, he stated that the policy had been changed and the SOP guide had not been updated.

Auditor Signature: Kenneth S. Petersen   **Date:** January 15, 2008

CORRECTIVE ACTIONS TAKEN: (To be completed by Auditee)
Based on the auditor's observations listed above, the following corrective actions were taken:
1. The restroom cleaning policy had been changed December 15, 2007. Verbal instructions were given to maintenance supervisor on December 15th, however the SOP Guide had not been properly updated. The new restroom cleaning policy has been updated in the SOP guide and copies distributed to all maintenance personnel who perform that job function.
2. Management has been reminded that any verbal changes to company policy must be documented in the company's food safety plan. All supervisors were also notified that if verbal instructions that supersede written company policy are not followed up with new written instructions within 7 days, the incidents are to be reported to the Vice President of Operations.

Signature: Ed Range   **Date:** January 17, 2007

Figure 17.2. An example of Notice of Correction Action.

not know they were required to wear hairnets, or that the auditee is not supplying enough hairnets for the number of employees in the field. The root-cause corrective action would have to examine the implementation of this policy and make sure that training is provided to employees; that employees are made aware of, understand, and abide by the policy; and that the supply of hairnets is sufficient to ensure compliance with the audit standard.

Conclusions

Third-party audits are an important component of modern food safety policy. These voluntary, nonregulatory audits serve as tools for major retailers, food service providers, and government agencies to verify that the fruits and vegetables they purchase are grown under established good agricultural practices. They are not in themselves guarantors that produce is always safe, but they do give some assurances that produc-

ers and processors are doing everything they can to minimize the risks of microbial contamination. If the federal government institutes mandatory GAPs in the future, third-party audits will provide some assurance to consumers and buyers that those regulations are being followed.

References

California Department of Food and Agriculture. 2007. California Leafy Green Products Handler Marketing Agreement, 2007. Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens. Sacramento, CA. Available at http://www.caleafygreens.ca.gov/members/resources.asp, accessed September 30, 2008.

LaBorde L, 2000. Third Part Audits—New Demands for Assurances of Food Safety. Mushroom News 48(9):4–6, September, 2000. Available at http://foodsafety.cas.psu.edu/mush/sept_2000.pdf, accessed September 30, 2008.

Russell, JP (Ed), 2000. *The American Society for Quality Audit Handbook*, 292 pp. ASQ Quality Press, Milwaukee, WI.

Surak JG and Wilson S (eds.), 2007. *The Certified HACCP Auditor Handbook*, ASP Quality Press Milwaukee, Wisconsin, page 283.

U.S. CDC (Centers for Disease Control and Prevention—Outbreak Response and Surveillance Team), 2008. Outbreak Surveillance Data. Available at http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm, accessed September 30, 2008.

U.S. Department of Agriculture, 2006. Fresh Fruits and Vegetables: Required Good Agricultural Practices (GAP) Verification. Available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5054457, accessed September 30, 2008.

U.S. Environmental Protection Agency, 2007. Guidance for Preparing Standard Operating Procedures (SOPs). EPA QA/G-6 April 2007. Available at http://www.epa.gov/QUALITY/qs-docs/g6-final.pdf, accessed September 30, 2008.

U.S. Food and Drug Administration—Center for Food Safety and Applied Nutrition, 1998. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. Available at http://www.cfsan.fda.gov/~dms/prodguid.html, accessed September 30, 2008.

U.S. Food and Drug Administration—Center for Food Safety and Applied Nutrition, 2005. Commodity Specific Food Safety Guidelines for the Melon Supply Chain. Available at http://www.cfsan.fda.gov/~dms/melonsup.html, accessed September 30, 2008.

U.S. Food and Drug Administration—Center for Food Safety and Applied Nutrition, 2006. Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain. Available at http://www.cfsan.fda.gov/~dms/tomatosup.html, accessed September 30, 2008.

U.S. Food and Drug Administration—Center for Food Safety and Applied Nutrition, 2008. Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables. Available at http://www.cfsan.fda.gov/~dms/prodgui4.html, accessed September 30, 2008.